Replacement Claims

1 to 122. *CANCELLED*

123. *(Currently amended)* A concentrated liquid hormone composition for use in compounding a pharmaceutical product for topically delivering one or more steroid hormones to a subject in need of hormone replacement therapy, ~~comprising:~~

~~a) one or more naturally occurring steroid hormone(s); and~~

~~b) a combination of penetration enhancing solvents that promotes delivery of the steroid hormone(s) through the dermis following topical administration;~~

~~with the proviso that the composition is essentially free of water; and~~

~~wherein the combination of penetration enhancing solvents comprises~~

comprising one or more naturally occurring steroid hormone(s) dissolved in a solvent mixture consisting of ethoxy diglycol and propylene glycol.

124. *CANCELLED*

125. *(Currently amended)* The concentrated liquid hormone composition of claim 123, wherein the ~~solvents in the composition consist essentially of~~ solvent mixture is about 50% ethoxy diglycol and about 50% propylene glycol (vol/vol).

126. *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising one or more estrogen(s) at a total concentration of at least 40 mg per gram.

127. *(Currently amended)* The concentrated liquid hormone composition of claim 126, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

128. *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising at least one androgen at a concentration of at least 150 mg per gram.

129. *(Currently amended)* The concentrated liquid hormone composition of claim 128, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

130. *(Currently amended)* The concentrated liquid hormone composition of claim 123, comprising at least one progestagen at a concentration of at least 200 mg per gram.

131. *(Currently amended)* The concentrated liquid hormone composition of claim 130, wherein said progestagen is selected from progesterone and pregnenolone.

132. *(Currently amended)* A concentrated liquid hormone composition for use in compounding a pharmaceutical product for delivering hormones to a subject in need of hormone replacement therapy, comprising a plurality of different naturally occurring estrogens dissolved ~~or suspended in one or more solvent(s) or wetting agent~~ in a solvent mixture of ethoxy diglycol and propylene glycol at a total concentration of least 6 mg of estrogens per gram.

133. *CANCELLED*

134. *(Previously presented)* The concentrated composition of claim 132, wherein the composition comprises about 40 mg of estrogens per gram.

135. *(Currently amended)* The concentrated composition of claim 132, wherein the estrogens are ~~estriol and estradiol, and optionally~~ estriol, estradiol, and estrone.

136. *CANCELLED.*

137. *(Previously presented)* The concentrated composition of claim 135, wherein the ratio of estriol, estradiol, and estrone by weight is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

138. *CANCELLED*

139. *(Withdrawn) (Currently amended)* A method for preparing the concentrated composition of any of ~~claims 123-138~~ claims 123, 125 to 132, 134 ,135, and 137, comprising:

a) combining said steroid hormone(s) with said solvent(s) ~~or wetting agent~~; and

b) processing said combination in an ointment mill or homogenizer to decrease particle size of said hormone(s) in the combination.

140. *(Currently amended)* A plurality of concentrated hormone compositions according to any of ~~claims 123-138~~ claims 123, 125 to 132, 134 ,135, and 137.

141 to 159. *CANCELLED*

160. *(Currently amended)* A method for compounding a pharmaceutical product for administering one or more hormones to a consumer in need of hormone replacement therapy, whereby the product is custom tailored for each individual consumer, the method comprising:

~~a) obtaining one or more concentrated reagent compositions, each comprising one or more steroid hormone(s) in one or more penetration enhancing solvent(s) or wetting agents;~~

a) obtaining a plurality of concentrated liquid reagent compositions, each comprising one or more steroid hormone(s) dissolved in one or more solvent(s);

b) ascertaining the needs of an individual consumer;

c) compounding ~~one or more~~ a plurality of said concentrated reagent composition(s) into said pharmaceutical product at a ratio that is custom tailored to the individual needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

161. *(Previously presented)* The compounding method of claim 160, wherein the needs of each consumer are ascertained by way of a prescription from a doctor for replacement of particular hormone(s) each in a particular amount.

162. *CANCELLED*

163. *(Previously presented)* The compounding method of claim 160, wherein concentrated reagent composition(s) are compounded with a suitable pharmaceutical carrier to produce a pharmaceutical product formulated as an ointment, cream, gel or paste.

164. *(Currently amended)* The compounding method of claim 160, wherein the ~~penetration enhancing~~ solvents are ethoxy diglycol and propylene glycol.

165. *(Currently amended)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains one or more estrogen(s) dissolved at a total concentration of at least 40 mg per gram.

166. *(Previously presented)* The compounding method of claim 165, wherein said estrogen(s) are selected from estriol, estradiol, and estrone.

167. *(Currently amended)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains a plurality of estrogen(s) dissolved at a total concentration of between 10 and 60 mg of estrogens per gram.

168. *(Previously presented)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one androgen at a concentration of at least 150 mg per gram.

169. *(Previously presented)* The compounding method of claim 168, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

170. *(Previously presented)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one progestagen at a concentration of at least 200 mg per gram.

171. *(Previously presented)* The compounding method of claim 170, wherein said progestagen is selected from progesterone and pregnenolone.

172. *(Previously presented)* The compounding method of claim 160, comprising combining a plurality of concentrated reagent compositions, each containing a different estrogen.

173. *(Previously presented)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol and estradiol.

174. *(Previously presented)* The compounding method of claim 173, wherein the ratio of estriol:estradiol by weight in the final product is 5:5, 6:4, 7:3, 8:2, or 9:1.

175. *(Previously presented)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol, estradiol, and estrone.

176. *(Previously presented)* The compounding method of claim 175, wherein the ratio of estriol, estradiol, and estrone by weight in the final product is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

177. *(Currently amended)* The compounding method of any of ~~claims 160-176~~ claims 160, 161, and 163 to 176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying the identity of the hormone(s) in the product according to the color of the pharmaceutical product after compounding.

178. *(Currently amended)* The compounding method of any of ~~claims 160-176~~ claims 160, 161, and 163 to 176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying that the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

179. *(Currently amended)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a patient for replacement or supplementation of one or more hormone(s); and

b) prescribing for the patient a pharmaceutical product that is compounded according to the method of any of ~~claims 160-176~~ claims 160, 161, and 163 to 176, whereby the product is customized to the individual needs of the ~~subject~~ patient determined in step a).

180. *(Currently amended)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a consumer for replacement or supplementation of one or more hormone(s);

b) compounding a pharmaceutical product according to the method of any of ~~claims 160-176~~ claims 160, 161, and 163 to 176, whereby the product is customized to the individual needs of the ~~subject~~ consumer determined in step a); and

c) providing said pharmaceutical product to the consumer.

181. *CANCELLED*

182. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 177, comprising:

a) observing the color of the pharmaceutical product after compounding;

b) deducing the identity of the hormone(s) in the product from the color; and

c) comparing the hormone(s) in the product with the hormone(s) that need supplementation in a particular consumer.

183. *CANCELLED*

184. *(Previously presented)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 178, comprising determining whether the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.